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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,943	03/08/2000	KUBER T. SAMPATH	CIBT-P01-570	7342

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EXAMINER

GAMETT, DANIEL C

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/423,943	Applicant(s) SAMPATH ET AL.	
	Examiner Daniel C. Gamett, PhD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-15,17-29,76 and 123-125 is/are pending in the application.
 4a) Of the above claim(s) 5,29 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,8-15,17-28 and 123-125 is/are rejected.
- 7) ☒ Claim(s) 123 is/are objected to.
- 8) ☒ Claim(s) 1,3,5-15,17-29,76 and 123-125 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendments of 10/11/2005 have been entered in full. Claims 1, 3, 5-15, 17-29, 76, and 123-125 are pending. Claims 5, 29, and 76 were withdrawn from examination as claiming non-elected subject matter. Claims 1, 3, 6, 8-15, 17-28, and 123-125 are under consideration insofar as they read upon elected species 'renal tissue' in this office action.
2. All prior objections/rejections not specifically maintained in this office action are hereby withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's assistance in clarifying the continuing data for this application is requested. The bibliographic data sheet indicates that this application is 371 of PCT/US98/10909 with no further parent data listed or claimed. Our records indicate that PCT/US98/10909 is a continuation of U.S. application number 08/866827 and also claims priority from U.S. provisional applications 60/048062 and 60/048063. Applicant's declaration filed 03/08/2000 did include a claim of benefit of applications 08/866827, 60/048062 and 60/048063, but this claim was not acknowledged for reasons unknown to the examiner. In the meantime, the status of application 08/866827 has changed. An amendment to place an updated claim of priority as the first sentence of the specification would clarify the matter. Applicants' attention is directed to the following notice issued on March 18, 2003:

Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. 119(e), 120, 121, and 365(c):

Benefit claims under 35 U.S.C. 120 must include a specific reference to the earlier filed (nonprovisional) application for which a benefit is sought. A "specific reference"

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requires: (1) the identification of the prior (nonprovisional) application by application number; and (2) an indication of the relationship between the nonprovisional applications, except for the benefit claim to the prior application in a continued prosecution application (CPA). The relationship between any two nonprovisional applications will be an indication that the later-filed nonprovisional application is either a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application. When there are benefit claims to multiple prior nonprovisional applications (e.g., a string of prior nonprovisional applications), the relationship must include an identification of each nonprovisional application as either a continuation, divisional, or continuation-in-part application of a specific prior nonprovisional application for which a benefit is claimed. The identification is needed in order to be able to verify if copendency exists throughout the entire chain of prior nonprovisional applications.

Objection Maintained

5. Applicants' intent to submit corrected drawings in response to the objection to the specification set forth in the prior office action is acknowledged. It is agreed that the drawings and their descriptions may be corrected without introduction of new matter. The objection will be maintained until the drawings are received.

New Claim Objections

6. Claim 123 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 123 had been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. As the indefiniteness has been removed by Applicant's amendment to claim 3, it is now clear that claim 123 does not further limit claim 3. As noted previously, the local defect site created in step (a) of claim 3 is a permissive site, according to the definitions given in the specification. Applicant's argument filed 10/11/2005 seems to be

directed toward a claim that specifies that the local defect site is permissive *at the time of administration of the candidate morphogenic protein*, which claim 123 is not.

Claim Rejections - 35 USC § 112

7. Claims 1, 3, 6, 8-15, 17-28, and 123-125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant's arguments filed 10/11/2005 have been fully considered but they are not persuasive. Applicant's arguments were directed mainly to the issue of guidance for step (a) in claims 1,3, and 125. Applicant's points regarding the creation of a defect site accessible to progenitor cells are well taken, but the rejection did not rest entirely on this issue; many aspects of the rejection were not addressed and are not overcome by the amendments. In particular, the specification does not include any example that is directly relevant to the elected species of renal tissue. The given examples do not establish a basis for predicting what will work for tissues not exemplified, as it is evident that each tissue has its own requirements. Contrary to Applicant's assertion, the present specification does not establish that OP-1 can be a positive control when the claimed method is practiced with renal tissue. The skilled artisan would need to reiterate the entire discovery process of the instant application in order to perform the claimed method is practiced with renal tissue.

Conclusion

8. No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

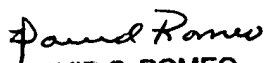
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
18 January 2006


DAVID S. ROMEO
PRIMARY EXAMINER